

EC Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of the manufacturer in accordance with the Council Directive 93/42/EEC in its currently valid version (Annex I) concerning medical devices.

Product:

Oxygen Sensor

Typ:

EnviteC	Viamed
OOM102-A	R-22VA

Classification:
(RL 93/42/EEC,
Annex IX)

Class IIa

CE mark:



Notified Body:

TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 Munich, Germany

Conformity
Assessment
Process:

Annex II, section 3 of the Directive 93/42/EEC

Particular
product
standard
applied:

ISO 80601-2-55

Issued by:

ENVITEC-WISMAR GMBH
Alter Holzhafen 18
D-23966 Wismar
Germany

Valid from:

2021-05-03

Valid until:

2024-05-26

Place, Date:

Wismar, 2021-05-03

Authorized Signature:


ppa. Marko Sprössel


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